

REMARKS

Reconsideration of the application is respectfully requested. Claims 20-40 are pending and at issue.

Obviousness-Type Double Patenting

Claims 20-40 have been provisionally rejected for obviousness-type double patenting over claims 36-46 of U.S. Patent Application No. 10/468,685, claims 20-34 of U.S. Patent Application No. 10/644,587, and claims 20 and 22-37 of U.S. Patent Application No. 10/644,588, in view of Applicant's allegedly admitted prior art. Applicant respectfully requests that these provisional rejections be held in abeyance because none of the patent applications containing the conflicting claims have been allowed or issued as patents.

Obviousness Rejection

Claims 20-40 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,943,590 ("Boegesoe") in view of the present specification. The Examiner cites Boegesoe as disclosing a method of treating depression using escitalopram, and cites the present specification as disclosing that clinical studies on depression show that non-response or resistance to selective serotonin reuptake inhibitors (SSRIs) is substantial. From this, the Examiner concludes that it would have been obvious for one of ordinary skill to treat depression in a patient who failed to respond to a non-escitalopram SSRI by administering escitalopram because, in the Examiner's view, Boegesoe discloses "escitalopram as being the more effective

enantiomer at inhibiting serotonin uptake.” Office Action, p. 5.

The rejection is respectfully traversed, and reconsideration is requested.

Claims 20-40 are not obvious over Boegesoe because, *inter alia*, this reference would not have motivated one of ordinary skill in the art to administer escitalopram for the treatment of depression in patients who have failed to respond to treatment with an initial, non-escitalopram SSRI, as called for in the pending claims.

The claimed patient population specifically contains certain treatment-resistant patients suffering from depression. In these patients, administration of an SSRI (other than escitalopram) has been shown to be ineffective in treating their depression. Given the failure of a first SSRI to produce an effective response in these patients, one of ordinary skill in the art would not have reasonably expected them to then respond to another member of the exact same drug class. In other words, since these patients have shown resistance to previous SSRI treatment, one of ordinary skill would have had no reasonable expectation that these same patients could be effectively treated with another SSRI. Rather, any reasonable expectation of success associated with SSRIs would be necessarily diminished in this population.

This is particularly so in view of the numerous other treatment options available for patients with depression, such as psychotherapy, monoamine oxidase inhibitors, tricyclic antidepressants, noradrenaline reuptake inhibitors, serotonin receptor modulators, and other atypical agents such as nefazodone and bupropion. Given this wide range of options, one of ordinary skill in the art would not have had the motivation to use a second SSRI to treat depressed patients after a first SSRI failed. In fact, one of ordinary skill would have been

discouraged by the patients' initial failure to respond to SSRI treatment, and would have more likely turned to a different drug class or method for treating such non-responsive patients.

Even if, *arguendo*, one of ordinary skill would have expected this treatment-resistant patient population to successfully respond to a second SSRI, this is merely a broad generalization and would have provided no reasonable expectation of success with respect to the efficacy of escitalopram in particular. Boegesoe does not cure this problem because one of ordinary skill in the art reading Boegesoe would understand that it generically discloses the use of escitalopram for the treatment of depressed patients, but provides no guidance as to whether or not this compound would be effective in the SSRI-resistant patients called for in the pending claims. The present specification discloses that a substantial percentage of patients do not respond to certain SSRIs even though SSRIs are a primary therapeutic option for the treatment of depression. *See* specification at p. 1, lines 12-19. Hence, even if one of ordinary skill in the art reasonably expected (albeit to a diminished degree) that a second SSRI would be effective in treating depression in non-responsive patients, the disclosure in Boegesoe would not have provided the requisite motivation to single out escitalopram from the several other known SSRIs as the SSRI of choice.

In summary, claims 20-40 are not obvious because one of ordinary skill in the art would not have been motivated to use escitalopram to treat depression in the treatment-resistant patient population called for in the present claims after a first member of this same class of drugs had proven unsuccessful, particularly because several other types of treatment options were known to those of skill in the art and would have therefore been more reasonably selected.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

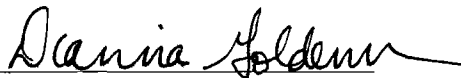
Conclusion

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: March 6, 2007

Respectfully submitted,

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